IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

NOVARTIS PHARMACEUTICALS CORPORATION and NOVARTIS AG	)	
Plaintiffs,	)	Civil Action No. 15-2905
v.	)	JUDGE:
	)	MAGISTRATE JUDGE:
ROXANE LABORATORIES, INC. and BOEHRINGER INGELHEIM ROXANE, INC.	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs, Novartis Pharmaceuticals Corporation and Novartis AG (collectively "Novartis"), by their attorneys, for their Complaint against Roxane Laboratories, Inc. ("Roxane") and Boehringer Ingelheim Roxane, Inc. ("BIR") (collectively "Defendants") allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, Sections 100 *et seq.* This action relates to an Abbreviated New Drug Application ("ANDA") filed by Roxane with the United States Food and Drug Administration ("FDA") for approval to market generic versions of Novartis' Gleevec® drug product.

THE PARTIES

2. Plaintiff Novartis Pharmaceuticals Corporation ("NPC") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 59 Route 10, East Hanover, New Jersey 07396.

3. Plaintiff Novartis AG ("Novartis AG") is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056, Basel, Switzerland.

4. Upon information and belief, defendant Roxane is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at 1809 Wilson Road, Columbus, Ohio 43228. Upon information and belief, defendant Roxane develops, manufactures, markets and distributes numerous generic drug products for sale and use throughout the United States, including in this judicial district.

5. Upon information and belief, Roxane is a wholly-owned subsidiary of Boehringer Ingelheim Corporation.

6. Upon information and belief, Roxane is registered to do business in Ohio and has designated its registered agent as CT Corporation System, 1300 East 9th Street, Cleveland OH, 44114.

7. Upon information and belief, defendant BIR is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 1809 Wilson Road, Columbus, OH 43228.

8. Upon information and belief, BIR is a wholly-owned subsidiary of Boehringer Ingelheim Corporation.

9. Upon information and belief, BIR is registered to do business in the state of Ohio and has designated its registered agent as CT Corporation System, 1300 East 9th Street, Cleveland OH, 44114.

10. Upon information and belief, BIR manufactures pharmaceutical drug products developed and marketed by Roxane, including tablets.

JURISDICTION AND VENUE

11. This action for patent infringement arises under 35 U.S.C. § 271.

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

13. Upon information and belief, Roxane and BIR are in the business of manufacturing, marketing, and selling pharmaceutical drug products, including generic pharmaceutical products.

14. Upon information and belief, Roxane and BIR directly, or indirectly through their affiliates and/or distributors, market, distribute, and sell their pharmaceutical products within and throughout the United States, including in the State of Ohio and throughout this judicial district. Upon information and belief, this Court has personal jurisdiction over Roxane and BIR for this reason and additional reasons set forth below.

15. Upon information and belief, Defendants are agents of each other and/or work in concert with each other with respect to the development, regulatory approval, marketing, sale, and distribution of pharmaceutical drug products throughout the United States, including into Ohio.

16. Upon information and belief, this Court has personal jurisdiction over Roxane and BIR because they purposefully avail themselves of the privilege of conducting activities within the State of Ohio by having their principal places of business at the same address in Columbus, Ohio and sharing common officers, directors and Managing Directors.

17. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) & (c) and 1400(b).

THE PATENTS IN SUIT

18. United States Patent No. 6,894,051 (the "'051 Patent") duly and legally issued on May 17, 2005 to inventors Jürg Zimmermann, *et al.* A true and correct copy of the '051 Patent is attached hereto as Exhibit A.

19. The '051 Patent is assigned to Novartis AG, and NPC is an exclusive licensee under the '051 Patent.

20. United States Reissue Patent No. RE43,932 (the "RE932 Patent") duly and legally issued on January 15, 2013 to inventors Jürg Zimmermann, *et al.* A true and correct copy of the RE932 Patent is attached hereto as Exhibit B.

21. The RE932 Patent is assigned to Novartis AG, and NPC is an exclusive licensee under the RE932 Patent.

ACTS GIVING RISE TO THIS ACTION

22. Plaintiff NPC holds an approved New Drug Application ("NDA") No. 21588 for Gleevec® tablets containing 100 mg and 400 mg imatinib mesylate, which was approved by the FDA on April 18, 2003.

23. By letter dated August 31, 2015 ("Roxane's Notice Letter"), Roxane notified Novartis International AG that it had submitted ANDA No. 207586 to the FDA under Section 505(j)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, offer to sell or sale of tablets containing 100 mg and 400 mg of imatinib mesylate (the "Imatinib Mesylate ANDA Tablets"). Upon information and belief, Roxane stated in its ANDA that its Imatinib Mesylate ANDA Tablets are bioequivalent to Novartis' 100 mg and 400 mg imatinib mesylate Gleevec® tablets.

24. In its Notice Letter, Roxane stated that its ANDA contained a "paragraph IV certification" that in Roxane's opinion, the '051 Patent and the RE932 Patent are invalid, unenforceable or will not be infringed by the manufacture, use, sale, or offer to sell of Roxane's Imatinib Mesylate ANDA Tablets.

25. In conjunction with filing its ANDA with a paragraph IV certification, Roxane was required under 21 U.S.C. § 355(j)(2)(B)(iii) to send its Notice Letter to the owner of each patent that is the subject of the certification, Novartis AG, and to the holder of the approved NDA for Gleevec®, NPC. Upon information and belief, Roxane did not send its Notice Letter to either Novartis AG or NPC.

26. As stated in its Notice Letter, Roxane's ANDA was submitted to obtain FDA approval to engage in the commercial manufacture, use and/or sale of Roxane's Imatinib Mesylate ANDA Tablets prior to the expiration of the '051 Patent and the RE932 Patent which are listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluation" (the "Orange Book") as being applicable to Novartis' Gleevec® tablets. On information and belief, Defendants intend to engage in the commercial manufacture, use and/or sale of Roxane's ANDA Imatinib Mesylate Tablets promptly upon receiving FDA approval to do so.

27. Roxane's filing of its ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell or sale of its Imatinib Mesylate ANDA Tablets, prior to the expiration of the '051 Patent and the RE932 Patent, constitutes infringement of one or more of the claims of those patents under 35 U.S.C. § 271(e)(2).

28. Defendants' commercial manufacture, use, offer to sell or sale of Roxane's Imatinib Mesylate ANDA Tablets, prior to the expiration of the '051 Patent and the RE932

Patent, would constitute infringement of the '051 Patent and the RE932 Patent under 35 U.S.C. § 271.

29. Upon FDA approval of Roxane's ANDA, Defendants will infringe the '051 Patent and the RE932 Patent by making, using, offering to sell, and/or selling Roxane's Imatinib Mesylate ANDA Tablets in the United States unless enjoined by this Court.

30. Roxane had notice of the '051 Patent and the RE932 Patent at the time of its infringement.

31. Novartis will be substantially and irreparably damaged and harmed if Defendants' infringement is not enjoined. Novartis does not have an adequate remedy at law.

WHEREFORE, Novartis respectfully requests the following relief:

(a) a judgment and decree that the '051 Patent and the RE932 Patent are valid and enforceable;

(b) a judgment and decree that Roxane has infringed one or more claims of the '051 Patent and the RE932 Patent in violation of 35 U.S.C. § 271;

(c) a judgment declaring that Defendants' making, using, selling, offering to sell or importing Roxane's Imatinib Mesylate ANDA Tablets will infringe the '051 Patent and the RE932 Patent;

(d) a judgment providing that the effective date of any FDA approval for Defendants to make, use or sell Roxane's Imatinib Mesylate ANDA Tablets be no earlier than the date on which last-expiring patent of the '051 Patent and the RE932 Patent expires, including any associated regulatory exclusivities;

(e) a judgment permanently enjoining Defendants from making, using, selling, offering to sell, or importing Roxane's Imatinib Mesylate ANDA Tablets until after

expiration of the '051 Patent and the RE932 Patent, including any associated regulatory exclusivities;

(f) if Defendants engage in the commercial manufacture, use or sale of Roxane's Imatinib Mesylate ANDA Tablets prior to the expiration of the '051 Patent and the RE932 Patent, a judgment awarding Novartis damages resulting from such infringement, increased to treble the amount found or assessed, together with interest;

(g) a judgment awarding Novartis attorneys' fees in this action pursuant to 35 U.S.C. § 285;

(h) a judgment awarding Novartis costs and expenses in this action; and

(i) a judgment awarding Novartis such further and other relief as this Court may deem just and proper.

Dated: October 13, 2015

ROETZEL & ANDRESS, LPA

/s/ Thomas L. Rosenberg

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